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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,441

11/10/2003

Gerald D. Cagle

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EXAMINER

ARIANI, KADE

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/705,441	<b>Applicant(s)</b> CAGLE ET AL.	
	<b>Examiner</b> KADE ARIANI	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 73-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 73-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***DETAILED ACTION***

The amendment filed on April 09, 2008, has been received and entered.

Claims 1-72 have been canceled.

Claims 73-77 are pending in this application and were examined on their merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74 and 76 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 74 and 76 contains the trademark/trade name Tetronic ®1304. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe one of the ingredients of the claimed composition and, accordingly, the

identification/description is indefinite.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 14, 15-19, 21-25, 27-29, 31-32, 34-36 and 38 under 35 U.S.C. 102(b) as being anticipated by Hunt et al. (US 5,897,833 A), is withdrawn due to Applicants amendments to the claims filed on 04/09/2008.

Applicant's arguments with respect to claims 73-77 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 73-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamien M. (Aust. Fam. Physician. 1999, Vol. 28, No. 8, p.817-828, Abstract) in view of Asgharian et al. (US Patent No. 6,139,646), and further in view of Hunt et al. (US 5,897,833 A), and further in view of Rothberg, S. (Science 1967, Vol. 156, p.90-93).

Claims 73-77 are drawn to a composition for assisting in the removal of human cerumen from the external ear canal, the composition comprising about 0.5% to about 15% w/v sodium bicarbonate, about 50 AU/ml to about 500 AU/ml methyl trypsin, about 1% to about 20% w/v glycerin (about 7% w/v glycerin), about 0.001% to about 0.1% w/v benzalkonium chloride (0.01% w/v benzalkonium chloride), and water, said composition having a pH about 7.5 to about 9.0, the composition further comprising about 0.1% to about 8% sodium citrate.2H<sub>2</sub>O (about 3% sodium citrate.2H<sub>2</sub>O) and about 0.05% to about 1% w/v Tetronic ®1304 (about 0.25% w/v), and said composition having a pH about 8.0 to about 8.3.

Kamien teaches a composition for assisting in the removal of human cerumen from the external ear canal comprising a solution of sodium bicarbonate, and further teaches a solution of sodium bicarbonate is the cheapest and most effective cerumenolytic (see Abstract).

Kamien does not teach methyl trypsin, glycerin, benzalkonium chloride, sodium citrate.2H<sub>2</sub>O, Tetronic ®1304, the claimed w/v percentages, and the composition having a pH about 7.5 to about 9.0 (about 8.0 to about 8.3).

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However, Asgharian et al. teach a liquid enzyme and disinfecting composition comprising methyl trypsin in amounts of 1-100 PAU/ml (or 1 -100 AU/ml) ( column 9, lines 13-14), glycerin (glycerol) (Example 3, ingredients, line 40), sodium citrate dehydrate (col.4 line 23-43).

Asgharian et al. also teach the enzyme composition is a multi-purpose composition (column 8 lines 56) and that the disinfecting solution may contain various components in addition to the enzyme, sodium citrate, poloxamine 1304 (Tetronic ®1304) (column 11 lines 57 and 59), benzalkonium halides (column 10 lines 37).

Asgharian et al. also teach sodium bicarbonate in an amount of at least 0.2% (Example 4).

Further motivation to modify the composition of Kamien is in Hunt et al. who teach a composition comprising an enzyme effective to remove debris or deposit (protein-based debris), the enzyme is trypsin, an effective amount of a preservative component in the liquid medium, the useful preservative component is benzalkonium chloride (column 6 lines 51-52).

Please note that at the time the invention was made it was well known in the art that cerumen plugs is consist of large amount of keratin debris (up to 60%) and that trypsin was able to solubilise keratin (see Rothberg, S.)

Hunt et al. also teach the activity of the enzyme activity is pH dependent. Moreover, at the time the invention was made it was well known in the art that the optimum pH of trypsin is about 8.0.

Furthermore, routine experimentation is widely used by one of ordinary skill in the art to determine optimum or workable ranges of particular parameters such as concentration (w/v %) of various ingredients of a cerumenolytic solution.

Therefore, in view of the above teachings, a person of ordinary skill in the art would have been motivated to modify the cerumenolytic composition as taught by Kamien according to the teachings of Asgharian et al. and Hunt et al. by adding a preservative composition comprising methyl trypsin in order to provide an improved cerumenolytic composition with a reasonable expectation of success because the art clearly teaches the keratinous nature of the cerumen plugs.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on 9:00 am to 5:30 pm EST Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon B Lankford/  
Primary Examiner, Art Unit 1651

Kade Ariani  
Examiner  
Art Unit 1651